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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/526,830

02/06/2006

Graham Edmund Kelly

700136.401USPC

5803

500

7590

02/25/2009

SEED INTELLECTUAL PROPERTY LAW GROUP PLLC

701 FIFTH AVE

SUITE 5400

SEATTLE, WA 98104

EXAMINER

PURDY, KYLE A

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

02/25/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<i>Office Action Summary</i>	Application No.	Applicant(s)	
	10/526,830	KELLY ET AL.	
	Examiner	Art Unit	
	Kyle Purdy	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2009.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 9-24 is/are pending in the application.
- 4a) Of the above claim(s) 10-19 and 21-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9, 20 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2 pages (01/13/2009)</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/13/2009 has been entered.

Status of Application

2. The Examiner acknowledges receipt of the arguments and amendments filed on 01/13/2009 wherein claim 9 has been amended.

3. Claims 1-5, 9, 20 and 24 are presented for examination on the merits. Claims 10-19 and 21-23 stand as withdrawn. The following rejections are made.

Response to Applicants' Arguments

4. Applicants arguments filed 01/13/2009 regarding the objection of claims 9 and 20 made by the Examiner have been fully considered and they are found persuasive. This rejection has been overcome by amendment to the claims Applicants.

5. Applicants arguments filed 01/13/2009 regarding the rejection of claims 1-3, 5-9, 20 and 24 made by the Examiner under 35 USC 103(a) over Kelly (WO 98/08503), evidenced by Sinha et al. (Photochem. Photobiol. Sci., 2002) have been fully considered and they are found persuasive. This rejection has been overcome by Applicants arguments.

6. Applicants arguments filed 01/13/2009 regarding the rejection of claim 4 made by the Examiner under 35 USC 103(a) over Kelly (WO 98/08503) in view of Fleming et al.

Art Unit: 1611

(Cancer, 1994), evidenced by Sinha et al. (Photochem. Photobiol. Sci., 2002) have been fully considered and they are found persuasive. This rejection has been overcome by Applicants arguments.

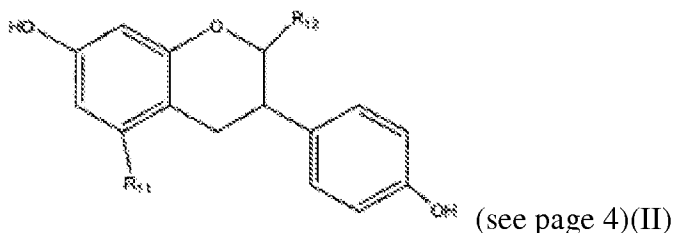
New Rejections
Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-5, 9, 20 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly et al. (WO98/08503; of record) in view of Kelly et al. (WO 99/36050, published 07/22/1999), evidenced by Sinha et al. (Photochem. Photobiol. Sci., 2002, 1,225-236; of record).

9. Kelly et al. ('Kelly 98) is drawn to therapeutic methods and compositions involving isoflavones. It is taught that compound 10 having the following molecular structure



wherein when both R1 and R2 are hydrogen, the resulting compound is dehydroequol (see page 27). It is taught that dehydroequol can be used for the treatment of diseases associated with oxidant stress including cancer and sunlight induced skin damage. Such conditions are generally regarded to be associated with oxidant stress, and the above

Art Unit: 1611

compound treats diseases associated with oxidant stress. It is taught that dehydroequol is highly effective antioxidant (see page 31) which according to the specification and the Example 6, is directly related to the treatment of cancer. Example 6.1 illustrates that dehydroequol is a potent free radical scavenger (see page 32). The compound may be carried in a therapeutic composition such as a cream wherein the active compound is present at a concentration from about 0.5% to 2% (see page 11). It is noted that the cream can be formulated as a cosmetic skin cream to prevent skin aging such as in a sun screen or a shampoo (see page 12).

10. Kelly fails to teach the instantly claimed compound. Moreover, Kelly fails to teach administering the compound after exposure to UV radiation.

11. Kelly ('Kelly 99) is directed to composition and methods for protecting skin from UV induced damage. The compositions of the method contain an extract of soy or clover and/or isoflavone compounds such as equol and dehydroequol (see abstract). The compositions are to be administered post UV exposure. It is taught that the compositions may protect the skin from UV induced damage when applied post UV exposure (see pages 1-3; see instant claim 1). Moreover, it's taught that in UN-exposed skin, damage to DNA culminates in carcinogenesis, the most common tumor being basal cell carcinoma, followed by squamous cell and more rarely malignant melanoma (see page 1; see instant claim 4).

12. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teaching of Kelly98 with Kelly98 with a reasonable expectation of success in arriving at a method utilizing a compound capable of enhancing the body defense against UV induced damage. Kelly98 teaches that the

Art Unit: 1611

compound dehydroequol is capable of treating conditions associated with oxidant stress such as cancer and that the compound is highly effective at scavenging free radicals. Although the reference does not specifically teach the elected species, it does teach a structurally analogous compound (compare structures 1 and 2). The major difference between the elected species and the species taught by Kelley is the presence of a methyl group. However, the presence of a methyl group in place of a hydrogen does not patentably distinguish the instant species over the prior art species. It is well established that a methyl functionality is structurally analogous to a hydrogen, and absent any secondary results, the elected compound would possess the same functional properties as dehydroequol. With respect to the limitations of instant claim 5, they are obvious. It is well known in the art that free radical formation is known to induce DNA damage through the formation of CPDs (cyclobutane pyrimidine dimmers) (see Sinha et al. (Photochem. Photobiol. Sci., 2002, 1,225-236). Thus, by implementing a compound that scavenges free radicals, it would necessarily reduce the formation of CPDs (i.e. promote repair and reduce potential of DNA damage due to UV-exposure). With respect to the time course of treatment regarding before, during of after UV exposure, this is also obvious. Kelly99 teaches that by applying isoflavone compositions post UV-exposure protects the skin from UV damage. One would have been motivated to apply the compounds and compositions of Kelly98 to the skin after UV-exposure. Thus, the invention as a whole is *prima facie* obvious to one ordinarily skilled in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Kyle Purdy/
Examiner, Art Unit 1611
February 19, 2009*

*/David J Blanchard/
Primary Examiner, Art Unit 1643*